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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,373

01/17/2006

Vladimir Sheiman

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09/16/2009

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EXAMINER

OSTRUP, CLINTON T

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,373	<b>Applicant(s)</b> SHEIMAN, VLADIMIR	
	<b>Examiner</b> CLINTON OSTRUP	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18, 19 and 21-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 21-36 is/are rejected.
- 7) ☒ Claim(s) 22-23 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/23/05 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/14/06 &amp; 6/3/08</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This Office Action is in response to Applicant's second preliminary amendment filed 11/6/2007. As directed by the second preliminary amendment, claims 1-17, 20 & 37-38 have been cancelled and claim 18 has been amended. Thus, claims 18-19 and 21-36 are pending in this application.

#### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It was not executed in accordance with either 37 CFR 1.66 or 1.68.

3. The Declaration filed 1/17/2006 is defective because it is not signed; or, not signed in the space marked for Inventor's Signature.

#### ***Drawings***

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because the lines, numbers, and letters are not uniformly thick and well defined. Figure 2 is further objected to because it has lines pointing to specific portions of the device without corresponding reference characters. Reference character "99" in figure 4 has been used to designate two different parts.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the

description: reference characters 99 (figure 4) & 176 (figure 10) lack antecedent basis in the specification.

6. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because figures 7-9 cannot be clearly seen.

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

8. The amendment filed March 7, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention.

The added material which is not supported by the original disclosure is as follows: The amendment to the specification to add "another aspect of the invention" is considered new matter. The new matter begins at page 4, "According to another aspect of the invention there is a nebulizer..." to the end of page 5. Applicant has not pointed

to any particular portion of the specification, drawings, or claims, as originally filed, to provide support for the added matter. Moreover, applicant has not stated that no new matter has been added by the amendment and specifically utilizes the amended specification to provide "Support for the new added claims and amendments can be found in the amended specification and the PCT priority document." See: page 12, first paragraph.

Thus, the material added does not have support in the application as originally filed and is considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action

### ***Claim Objections***

9. Claims 22-23 and 34 are objected to because of the following informalities: Claim 22 is objected to because of the terminology "for form" in line 2. For examination purposes, this terminology was read as "for forming;" however, appropriate correction is required.

Claim 23 is objected to for the term "across-sectional area" in line 3. For examination purposes, this terminology was read as "a cross sectional area;" however, appropriate correction is required.

Claim 34 is objected to because of the terminology "fo the tubular energy transmitter" in line 2. Fro purposes of examination this terminology was read as "of the tubular energy transmitter;" however, appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 23-24 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is confusing because it is unclear what is meant by "such that the positive pressure of the aerosol within the aerosol induces a pressure drop along the aerosol tube which propels the aerosol through the tube." Is there an aerosol within the aerosol, or, is the positive pressure of the aerosol causing the pressure drop along the aerosol tube and the subsequent drop in pressure propels the aerosol through the tube (e.g. a vacuum is created)?

Claim 24 is confusing because it is unclear if "at its opposite end" is referring to the aerosol tube or the tubular energy transmitter.

The terminology "minimal acoustic energy loss" in claim 36 is relative terminology which renders the claim indefinite. The terminology "minimal acoustic energy loss" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how minimal the acoustic energy loss must be to be included or excluded by the claim; therefore, the scope of the claim is unascertainable.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 18-19, 22, 30, 32, and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheiman (5,908,158) and further in view of Chen (6,152,383).

Cheiman discloses a nebulizer (figure 1) comprising: a container (2) adapted to contain a liquid (6) to be nebulized; and an energy source (1) being operatively coupled to the container for nebulization of the liquid (12) and being configured for transmission of energy to a focal region (peak of fountain 12) of the liquid which is forced toward an opposite end of the tubular member.

However, Cheiman lacks a tubular energy transmitter having one end immersed in the liquid proximate the container.

Chen teaches an ultrasonic nebulizer with a tubular energy transmitter (3 transmits vibration energy and guides the wave through the tube) having one end immersed in the liquid proximate the container. See: figures 1-4.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the nebulizer disclosed by Cheiman by using a tubular energy transmitter that has one end immersed in the liquid proximate the container in order to form a nebulizer that provides an ultrasonically nebulized liquid that is concentrated and can be guided directly to the patient.

Regarding claim 19, Cheiman discloses an energy source (1) that is positioned below the container.

Regarding claim 22, the combined references teach a tubular energy transmitter (3 of Chen) that vibrates at a frequency (via the ultrasonic vibrator 4 of Chen) for forming an aerosol, as disclosed by Cheiman, proximate the opposite end of the energy transmitter (See: figures 1 and 5-8 of Cheiman).

Regarding claim 30, Cheiman discloses the energy source as an ultrasonic transducer (1) which can be used for transmission of ultrasonic radiation energy.

Regarding claim 32, Cheiman discloses the ultrasonic transducer (1) arranged to transmit ultrasonic energy to a focal region (peak of 12) of the liquid (6).

Regarding claim 34, Cheiman discloses a nebulizer wherein the diameter of the focal region (12) is substantially equal to the internal diameter of the tubular energy transmitter taught by Chen.

Regarding claim 35, it is the examiner's position that the tube forming the tubular energy transmitter, as taught by Chen, inherently has a higher acoustic impedance than the liquid.

Regarding claim 36, the acoustic impedance of the tubular energy transmitter (3 of Chen) is high enough to effect minimal acoustic energy loss during transmittal of the energy along the tubular energy transmitter.

14. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cheiman (5,908,158) in view of Chen (6,152,383), as applied to claim 18 above, and further in view of Higson et al (4,976,259).



The combined references disclose all the limitations of claim 21, except the tubular energy transmitter positioned so that said one end is proximate the bottom of the container.

Higson teaches an ultrasonic nebulizer with a tubular member being immersed in the liquid so that one end is proximate the bottom of the container. See: col. 6, lines 29-41 and Figure 10.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the ultrasonic nebulizer of the combined references by placing the tubular member proximate the bottom of the container, as taught by Higson, in order to form an ultrasonic nebulizer that utilizes a liquid to strike the tubular member and nebulize the liquid into droplets.

15. Claims 23-31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheiman (5,908,158) in view of Chen (6,152,383), as applied to claim 18 above, and further in view of Sheiman (6,379,616).

Regarding claim 23, the device disclosed by the combined references teaches a nebulizer (Figure 1 of Cheiman) with an aerosol tube (3 as taught by Chen); however, the combined references lack the tubular energy transmitter positioned about at least a portion of the tubular energy transmitter and having across-sectional area such that the positive pressure of the aerosol within the aerosol induces a pressure drop along the aerosol tube which propels the aerosol through the aerosol tube.

Sheiman discloses a tubular energy transmitter (46) positioned about at least a portion of the tubular energy transmitter tube (32, 38) and having across-sectional area

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such that the positive pressure of the aerosol (col. 2, lines 1-5) within the aerosol induces a pressure drop along the aerosol tube which propels the aerosol through the aerosol tube.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the ultrasonic nebulization device disclosed by the combined references by placing an additional energy transmitter around the tube, as taught by Sheiman, in order to increase the kinetic energy of the atomized particles thereby allowing for smaller particle sized and better lung absorption of the particles.

Regarding claim 24, Sheiman teaches an internal diameter of the aerosol tube (at 32) is greater than an internal diameter of the tubular energy transmitter (46) at its opposite end.

Regarding claim 25, Sheiman teaches the aerosol tube (32, 38) is positioned so that it is substantially coaxial with the tubular energy transmitter (46).

Regarding claim 26, Sheiman teaches the aerosol tube (32, 38) is connected to the opposite end of the tubular energy transmitter (46).

Regarding claim 27, the combined references teach an energy source (1 of Cheiman) that vibrates the liquid proximate the opposite end of the tubular energy transmitter.

Regarding claim 28, Sheiman teaches an aerosol tube (32, 38) which opens at its upper end (32) into an expansion chamber (formed inside 32) which in turn communicates with an outlet duct (36).

Regarding claim 29, Sheiman teaches the expansion chamber (inside 32) is adapted (via 36 & 40) to recirculate larger drops of the liquid back into the container (22).

Regarding claim 31, Cheiman teaches an ultrasonic transducer (1) that has a concave shaped surface (figure 1).

Regarding claim 33, the device of the combined references teaches one end of the tubular energy transmitter (3 of Chen) is proximate the focal point (peak of 12 created by 1 of Cheiman).

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771